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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CRD5060-PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/39401	International filing date *(day/month/year)* 23 November 2004 (23.11.2004)	Priority date *(day/month/year)* 25 November 2003 (25.11.2003)
International Patent Classification (IPC) or national classification and IPC IPC: USPC:		
Applicant CORDIS CORPORATION		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22 June 2005 (22.06.2005)	12 February 2006 (12.02.2006)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Kimberly D. Nguyen Telephone No. 571-272-2402

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/39401

Box No. I Basis of the report

1. With regard to the language, this report is based on:
   - ☒ the international application in the language in which it was filed.
   - ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
     - ☐ international search (under Rules 12.3 and 23.1(b))
     - ☐ publication of the international application (under Rule 12.4(a))
     - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
   - ☐ the international application as originally filed/furnished
   - ☒ the description:
     pages 1,3-11,13-14,16-17 as originally filed/furnished
     pages* 2,12 and 15 received by this Authority on 04 August 2005 (04.08.2005)
     pages* NONE received by this Authority on
   - ☒ the claims:
     pages 18-19 as originally filed/furnished
     pages* NONE as amended (together with any statement) under Article 19
     pages* NONE received by this Authority on
     pages* NONE received by this Authority on
   - ☒ the drawings:
     pages 1-7 as originally filed/furnished
     pages* NONE received by this Authority on
     pages* NONE received by this Authority on
   - ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:
   - ☒ the description, pages 2, 12, 15
   - ☐ the claims, Nos
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing (*specify*):
   - ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing (*specify*):
   - ☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/39401

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-5	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-5	NO
Industrial Applicability (IA)	Claims 1-5	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-2 and 4 lack an inventive step under PCT Article 33(3) as being obvious over Frederick et al. (US 6,112,502) in view of Bauer et al. (US 2003/0216969).

Frederick teaches a medical device inventory management system, comprising:

a medical device defining an expiration date (col. 63, lines 38+), in medical device packaging;

an tag (360, 358) affixed to the medical device packaging (356), the tag being initialized with an identification code (""Label 360 is an example of a position only label which includes machine readable indicia which indicates only the storage location and the medical item stored therein" (col. 41, lines 51+));

a reader (348, 538) defining a proximity distance at which an tag is readable, adapted to generate and receive signals to and from an tag, thereby reading the identification number from the tag;

a computer having memory loaded with software;

such that when the medical device is in proximity to the reader, the reader interrogates the tag to read the identification code into the computer memory; and when the medical device is removed from proximity to the reader (col. 41, lines 45+), the reader communicates the removal of that identification code to the computer memory (col. 6, lines 53+); and if the medical device is again placed in proximity to the reader, the reader will again interrogate the tag to read the identification code into the computer memory;

wherein the computer software is adapted to periodically communicate all identification codes of medical device tag in proximity to the reader to an inventory administrator; and to automatically communicate an alert to the inventory administrator if an inventory of medical devices is reduced below a preselected amount; and to automatically communicate an alert to the inventory administrator if a medical device has reached the expiration date or is within a preselected time period of the expiration date (col. 63, lines 38+) (col. 2, line 26 through col. 68, line 3).

Frederick fails to teach the tag is an RFID tag and the reader is an RFID reader.

Bauer teaches an RFID tag and the reader is an RFID reader for inventory management system.

Claims 3 and 5 lack an inventive step under PCT Article 33(3) as being obvious over Frederick as modified by Bauer and further in view of De La Huerga (US 2002/0084904).

De La Huerga teaches the medical device inventory management system further comprising a wristband reader (300 in fig. 6).

Claims 1-5 meet the criteria set out in PCT Article 33(4), and thus have the industrial applicability because the subject matter claimed can be made or used in industry.

---------- NEW CITATIONS ----------

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inventory and sends an event to an event router when an item is added to or removed from the inventory. The event router receives the event from the monitoring system and sends the event to one or more item tracking systems. The item tracking systems receive the event and update stored information about the item to reflect the event." (Column 1, lines 37-44.)

[0007] In a retail location, for example, an item tracking system may be part of an inventory management system used at a retail store, which has inventory having RFID tags or transponders. When tagged items entered or leave the store, an RFID monitoring system will note these "inventory events." Alternately, when tagged items are removed from the shelf, or are replaced on the shelf, the RFID system will record these events. Also, the item tracking system may obtain alerts when an inventory level of a certain product falls below a certain amount, indicating that the product should perhaps be replenished.

[0008] There are two types of RFID tags: passive and active. A passive tag has no power source for communications or data transmission, while an active tag has some kind of internal power source such as a battery. An active tag may also have some computing or processing capacity.

[0009] RFID tags are generally capable of being electronically initialized, and storing a digital identification code, which can be read directly from the tag using an RFID reader. Some tags are capable of holding much more information, and some are re-writable.

[0010] As far as the RFID reader, it may include a frame or housing, one or more antennas, a radiofrequency interrogator, a radiofrequency multiplexer, and a computing system. It may be provided with software of varying sophistication.

AMENDED SHEET

HTTPS over TCP/IP. The software protocol between the client and the server software may be SOAP, and the server may implement J2EE web services.

[0080] REMOTE (SERVER) SITE:

[0081] The remote site could be located at a site of the medical device manufacturer or another campus. Its main function is to provide centralized data repository for all local (Hospital) sites. In other words, this is the master database. In addition, the remote site provides user interface, which allows the following operations which can be executed by an administrator:

[0082] 1. View all automatically generated e-mails or alerts, warning of inventory levels below recommended levels.

[0083] 2. Generate, view and print product use or inventory reports, by local site or system-wide.

[0084] 3. Generate, view and print last-known inventory reports, per local site or system-wide.

[0085] 4. Generate, view and print summary inventory reports.

[0086] 5. Generate, view and print summary inventory usage reports.

[0087] 6. Generate, view and print product expiration reports.

[0088] 7. Generate, view and print product history reports.

[0089] 8. Generate an interface file which can be used for a data exchange with the billing system of the medical device manufacturer.

[0090] 9. Generate an interface file that can be used with the order management system of the medical device manufacturer. This feature can allow an administrator to communicate with the transponders on the medical device inventory, indicating expiration status as well as multiple other events. In effect, the inventory can then alert against its own use, or notify the master database to perform immediate replenishment.

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[00104] The handheld executes the software, which controls an RFID interrogator, which may be built into the handheld device. It also may provide a graphical interface to allow the following operations:

[00105] 1. Selecting the location at which inventory is being taken from a list of known locations. If the location is new, the software may allow it to be added to the list of locations. For local sites or hospitals with multiple locations, an RFID transponder may identify each location uniquely.

[00106] 2. Start or stop an RFID scanning cycle.

[00107] 3. Accept or cancel the results of an RFID scanning cycle.

[00108] 4. Establish dial-up or wireless connection to the remote site and upload inventory levels and inventory events to the master database.

[00109] Any data replication with the master database may be done via a web service in the same manner as with the smart shelf unit. In other words, the handheld system may be programmed to register inventory and inventory events as are possible with the smart shelf unit.

[00110] OPERATIONAL SCENARIOS:

[00111] The following is a description of one possible method of using an RFID system to manage medical device inventory:

[00112] 1. Product is packaged, labeled and affixed with a RFID transponder at a manufacturing site of choice. The data transfixed on the transponder and associated with the respective Product is communicated to the remote site and the master database.

[00113] 2. Product is shipped to a Local Site (Hospital). If the local site is equipped with RFID shelf, and that shelf is configured to automatically scan for inventory, it

AMENDED SHEET